PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

Proposing rule making related to Iowa get screened (IGS): colorectal cancer program and providing an opportunity for public comment

The Public Health Department hereby proposes to amend Chapter 10, "Iowa Get Screened: Colorectal Cancer Program," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code section 135.11.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 135.11.

Purpose and Summary

The proposed amendments update screening eligibility requirements for the program to align with federal recommendations from the United States Preventive Services Task Force (USPSTF). These amendments will encourage access to services and align with a Centers for Disease Control and Prevention (CDC) cooperative agreement that is in year two of a five-year program. Additionally, language is proposed to be removed in order to allow for diagnostic services for eligible Iowans who had an initial positive screening test performed outside the program.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to the Department's waiver provisions contained in 641—Chapter 178.

Public Comment

Any interested person may submit written comments concerning this proposed rule making. Written comments in response to this rule making must be received by the Department no later than 4:30 p.m. on October 12, 2021. Comments should be directed to:

Victoria Brenton Department of Public Health 321 East 12th Street Des Moines, Iowa 50319

Email: victoria.brenton@idph.iowa.gov

Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)"b," an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental

subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making actions are proposed:

ITEM 1. Amend rule 641—10.1(135) as follows:

641—10.1(135) Purpose. The Iowa get screened (IGS): colorectal cancer program is administered by the department. The goal of the IGS program is to reduce the incidence, mortality and prevalence of colorectal cancer in Iowa by increasing the number of men and women who receive colorectal cancer screenings. Through the program, colorectal cancer screenings, including but not limited to fecal immunochemical tests (FITs) and colonoscopies, are provided to eligible Iowans. Along with providing screenings, the program also facilitates supportive services and referral for diagnosis and treatment to Iowans with abnormal screening results. Iowans who are eligible to enter the program must be 50 45 to 75 years of age, be underinsured or uninsured, have incomes of up to 300 percent of the federal poverty level (FPL) and have an average or increased risk for developing colorectal cancer.

ITEM 2. Adopt the following <u>new</u> definition of "Stool DNA (sDNA) test" in rule **641—10.2(135)**: "Stool DNA (sDNA) test" means a test that uses stool samples to detect abnormal DNA and small amounts of blood shed into the stool from colon cancer or colon polyps.

ITEM 3. Amend paragraphs 10.3(2)"a" and "b" as follows:

- a. The IGS program provides reimbursement for the following screening tests, procedures, preparations and tissue analyses when those services are provided by a participating health care provider who has a provider agreement with the IGS program. Payment is based on Medicare Part B participating provider rates (Title XIX).
 - (1) Fecal immunochemical tests annually;
- (2) Colonoscopy every <u>10 ten</u> years from initial screen or as prescribed by a physician in accordance with USPSTF recommendations;
 - (3) Biopsy/polypectomy during a colonoscopy;
 - (4) Bowel preparation;
 - (5) Moderate sedation for colonoscopy;
 - (6) One office visit related to IGS program-covered colorectal cancer tests;
 - (7) One office visit related to colorectal cancer follow-up diagnostic test results;
- (8) Total colon examination with either colonoscopy (preferred) or double contrast barium enema if medically prescribed by doctor;
 - (9) Pathology services.;
 - (10) CT colonography (or virtual colonoscopy) as recommended by provider;
 - (11) Stool DNA (sDNA) test every three years;
- (12) Care or services for complications that result from screening or diagnostic tests provided by the IGS program at the discretion of the department and based on the availability of funds.
 - b. The IGS program does not provide reimbursement for the following:
 - (1) Screening tests requested at intervals sooner than recommended by the USPSTF;
 - (2) CT colonography (or virtual colonoscopy) as a primary screening test;
 - (3) (2) Computed tomography scans (CT or CAT scans) requested for staging or other purposes;
 - (4) (3) Surgery or surgical staging;
 - (5) (4) Any treatment related to the diagnosis of colorectal cancer;

- (6) Any care or services for complications that result from screening or diagnostic tests provided by the IGS program;
 - (7) (5) Medical evaluation of symptoms that make individuals at high risk for CRC;
- (8) Diagnostic services for participants who had an initial positive screening test performed outside of the program;
- (9) (6) Management and testing (e.g., surveillance colonoscopies and medical therapy) for medical conditions, including inflammatory bowel disease, ulcerative colitis or Crohn's disease;
- (10) (7) Genetic testing for participants who present with a history suggestive of a hereditary nonpolyposis colorectal cancer (HNPCC) or familial adenomatous polyposis (FAP); and
- (11) Use of propofol as anesthesia during endoscopy, unless specifically required and approved by the IGS program in cases where the participant cannot be sedated with standard moderate sedation; and (12) (8) Treatment for colorectal cancer.
 - ITEM 4. Amend paragraph 10.3(3)"c" as follows:
- c. If the enrolled participant has an abnormal colorectal cancer screening test, the health care provider or local coordinator shall provide to the participant a comprehensive referral directing the participant to appropriate additional diagnostic or treatment services. When the results of a FIT screen screening test are positive, the local coordinator shall work with the participant and enrolled health care provider to schedule a colonoscopy.
- ITEM 5. Renumber rules 641-10.5(135) to 641-10.9(135) as 641-10.4(135) to 641-10.8(135).
 - ITEM 6. Amend renumbered subrule 10.4(1) as follows:
- 10.4(1) Age. Individuals 50 ± 5 through 75 years of age shall be the target population to receive colorectal cancer screening.
 - ITEM 7. Amend renumbered subrule 10.4(6) as follows:
 - 10.4(6) *Ineligible*. The IGS program does not provide coverage for:
 - a. Individuals with Medicare Part B coverage.
 - b. Individuals 49 44 years of age and younger.
 - c. Individuals 76 years of age and older.
 - d. Individuals who do not have a primary care provider.
 - e. Individuals at high risk for developing colorectal cancer. Individuals at high risk include:
- (1) A genetic diagnosis of familial adenomatous polyposis (FAP) or hereditary nonpolyposis colorectal cancer (HNPCC),
 - (2) A clinical diagnosis or suspicion of FAP or HNPCC, or
 - (3) A history of inflammatory bowel disease (ulcerative colitis or Crohn's disease).
 - f. Individuals experiencing the following gastrointestinal symptoms:
 - (1) Rectal bleeding, bloody diarrhea, or very dark blood in the stool within the past six months;
 - (2) Prolonged change in bowel habits;
 - (3) Persistent/ongoing abdominal pain;
 - (4) Recurring symptoms of bowel obstruction; or
 - (5) Significant unintentional weight loss.
 - ITEM 8. Amend renumbered paragraph 10.5(1)"b" as follows:
- b. Upon enrollment, the participant shall be eligible for services for 12 months beginning from the date of enrollment, subject to restrictions in funding and program coverage as provided in subrules 10.6(2) 10.5(2), 10.6(3) 10.5(3) and 10.7(1) 10.6(1).
 - ITEM 9. Amend relettered paragraph 10.5(3)"b" as follows:
 - b. No longer meets the criteria set forth in rule 641 10.5(135) 641—10.4(135);

ITEM 10. Amend renumbered subrule 10.6(2) as follows:

10.6(2) In the event that the financial demand abates, the program director shall withdraw the financial shortfall certification, at which time the individual shall be eligible for program services in accordance with rule 641 - 10.5(135) 641 - 10.4(135).